



New Addiction Drug May be Blocked by FDA in the Midst of Opioid Epidemic

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A drug that can rival Sublocade is ready to hit the market?but it may be blocked by the FDA for several years, despite the opioid crisis.

Sublocade is currently the only injectable form of buprenorphine, the drug that blocks cravings associated with addiction. Buprenorphine usually comes in tablets and dissolvable film, but the injectable form Sublocade is used for its longer lasting effects.

If the company that makes Sublocade gets its way, its rival drug will be blocked by the FDA and it will be the only long-acting buprenorphine on the market for five more years. This is because of a quirk in federal law that may prevent the competing drug called Brixadi from going on sale until 2024.

?It's ready for market now,? said Mike Derkacz, CEO of Braeburn, which makes Brixadi. ?We are deemed safe and effective by FDA, but we are unable to make the product available to patients during this crisis.?

According to the National Institute on Drug Abuse, about 2.3 million people in the US were addicted to

prescription opioids or illicit opiates like heroin. 47,000 people died of an overdose that same year. The Trump administration later declared opioid addiction a public health emergency, just a month before Sublocade hit the market. This made medication-assisted treatment a priority.

The makers of Brixadi were therefore shocked to hear that the FDA only gave their product tentative approval in December. Derkacz said it doesn't make sense, since buprenorphine medications play such a key role in treating opioid addiction, especially now that there is an epidemic.

"There have been studies that show a reduction in mortality by 40% with buprenorphine," he said. "That keeps people alive. That gives people a chance to get back to their lives and recover fully."

More than 130 people in the US die of an opioid overdose every day. But a loophole in federal law might block Brixadi for a few more years.

"It's important to have multiple different treatment options for different patients, different circumstances," said Carolyn Bogdon, a family nurse practitioner from Medical University of South Carolina in Charleston, S.C.

Buprenorphine is an opiate, but it does not give people the same high, and it instead blocks the cravings associated with addiction. This helps people who are going through medical detox while recovering from their addiction because they don't feel the intense cravings caused by withdrawal.

Sublocade was first approved for sale in 2017. Like any new drug, it was granted three years of exclusive access to US markets. That time is up next year. But in December, the Food and Drug Administration told Braeburn that it might have to wait four more years because Sublocade was designated as an "orphan drug" which means it has seven years of exclusive access.

Normally, orphan drugs are medications that treat illnesses affecting fewer than 200,000 people a year. But because of the opioid epidemic, more people are dying of drug overdose. [Click the link to see Bakersfield's top rehab placement programs.](#)

Indivior created its first buprenorphine-based drug in the 1990s. At the time, treating addiction with other drugs was not mainstream. There were methadone clinics in some US cities, but they were heavily regulated by law. The company asked the FDA to give it orphan status because Indivior said it had little hope of earning back its investment in Subutex and needed extra time with no competition. Few drugs have received orphan status this way, but it made sense to the FDA at the time.

Subutex hit the market in 2002 soon after its orphan designation was granted. Since then, the company has made billions in revenue from sales of the drug, as well as its successors, Suboxone and Sublocade.

Indivior wrote: "Indivior stands by FDA's decision, which was supported by both the law and the facts at that time."

Derkacz said that Braeburn has asked the FDA to revoke Sublocade's orphan status, and an FDA spokeswoman said that the agency is actively considering that request in light of the epidemic.

Long-acting treatments for addiction have important benefits for certain patients. For starters, patients don't have to remember to take their medication every day. They can avoid going to the drugstore because the medication is injected once a month.

"It provides a little bit more anonymity for patients that don't want to disclose that they have an opiate use disorder," said Michelle Lofwall from the University of Kentucky. "Some patients have felt stigmatized when going to the pharmacy like they don't feel like they're necessarily treated all that well once they show their prescription."

Lofwall is aware of the differences between Sublocade and Brixadi as she is one of the few health care providers who has used both medications. She believes that patients should have access to both options.

"From a public health perspective, and just as a provider physician trying to treat patients, they need to have all the options," she said. Being on the right drug "literally can save their life."

If someone in the family is struggling with opioid or alcohol addiction, it is important to seek help. A combination of medical detox and behavioral therapy can go a long way in the fight against drug abuse. But because every individual is affected by addiction differently, a comprehensive program tailored to their specific needs is necessary. Look for a nearby addiction treatment facility today and find out how drug treatment programs work.

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